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DEVICE FOR THE IMPLANTATION AND FIXING OF HEART VALVE PROSTHESES

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The invention relates to a device for the implantation and fixing of heart valve prostheses with a heart valve prosthesis (4) fixed to a self-expanding locating support (1). The aim of the invention is to implant heart valve prostheses in a minimally-invasive manner with increased positional accuracy in a heart chamber of a patient. Said aim is achieved, whereby a self-expanding locating support is housed in a cartridge (6) which may be connected to a catheter in a folded form. Support hoops (2) are embodied on the proximal side of the locating support which may be introduced into the pockets of the heart valve of a patient. The release of the support hoops from the cartridge is achieved by means of a first given movement of the cartridge. Further elements of the locating support with the heart valve prosthesis are released to give complete expansion and location by means of at least one further movement of the cartridge and/or the catheter.

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(54) DEVICE FOR THE IMPLANTATION AND FIXING OF HEART VALVE PROSTHESES

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(72) Inventor:
FIGULLA, Hans-Reiner
07749 Jena (DE)
FERRARI, Markus
07747 Jena (DE)
GUYENOT, Volker
07749 Jena (DE)
DAMM, Christoph
07743 Jena (DE)
MUELLER Ekkehard
99425 Weimar (DE)

(73) Patent Holder:
Figulla, Hans-Reiner
07749 Jena (DE)
Ferrari, Markus
07747 Jena (DE)
Fraunhofer-Gesellschaft for the promotion of applied research e.V.
80686 Munich

(74) Representative: Pfenning, Menig & Partner Gbr
Gostritzer Strasse 61-63
01217 Dresden (DE)

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Description

[0001] The invention relates to a device for the implantation and fixing of heart valve prostheses with a heart valve prosthesis fixed to a self-expanding anchoring support, whereby the heart valve prosthesis may be a biological or a mechanical heart valve prosthesis.

[0002] It may be implanted transluminally and be used for the implantation of a heart valve prosthesis as an aortic or pulmonary valve.

[0003] Solutions were sought for how such implantations could occur in a minimally invasive manner based on the heart valve prosthesis implantations, for which a surgical opening of the thorax of patients was required and for which the respective patient had to be connected to a heart-lung-machine over the period of the surgical intervention, which was impossible for a large number of high risk patients and which demanded a protracted post-operative treatment phase.

[0004] Various solutions are known for this. A self-expanding heart valve prosthesis for implantations in human bodies through a system of catheters using a collapsible and expandable stent connected with the heart valve is known in DE 195 46 692 C2. Such a self-expanding heart valve prosthesis can be guided through an artery in the groin with the help of a system of catheters up to the implantation location on the heart. After reaching the implantation location a stent of this type, which in its longitudinal direction is pieced together from several self-expanding stent segments that can be snaked relative to one another, can then be deployed successively. After the deployment the heart valve prosthesis is also able to be anchored with the assistance of support hoops at least in the area close to the heart in the respective blood vessel.

[0005] In the process the actual heart valve prosthesis is situated directly in the proximal area of the stent.

[0006] A device for the fixing and anchoring of heart valve prostheses, which essentially comprises filament shaped elements connected with one another, is described in DE 100 10 074 A1. Various hoops are used in the process to achieve a secure attachment and bracing of a heart valve prosthesis. The device described therein uses three pairs of hoops each the same, which are spaced at 120° to one another. These hoops are connected to one another through flexures whereby the flexures satisfy the function of pivots.

[0007] In addition there are hoops bowed in opposition to one another that form the most uniform arms of a lever possible, in order to be able to achieve a secure hoop attachment even with peristaltic movements on the heart and blood and reliable sealing of an implanted and anchored heart valve prosthesis.

[0008] However, in the case of the known solutions there exists the danger of an abnormal implantation of heart valves. This essentially concerns the exact positioning and the angular orientation of the heart valve prostheses to be implanted. At the same time the removal of an incorrectly positioned, implanted heart valve prosthesis is only possible, if at all, at great expense with the known solutions, whereupon in this case a further surgical intervention may be necessary at a minimum.

[0009] Abnormal implantations of that ilk lead to leakages (valvular insufficiency) and correspondingly to significant stresses of the ventricle. For example, closure of the passages of the coronary vessels (the coronary vessels) may result if an implantation of a heart valve prosthesis occurred too far above the actual heart valve plane and with this to fatal ischemic stroke with cardiac infarction.

[0010] With the implantation technologies, in the case of which heart valve prostheses until now have been guided up to the implantation location on the heart through groin arteries with minimal invasiveness, the introduction occurs with the use of a guide wire and the help of catheters, whereby even the conventional balloon catheters have been used.

[0011] The introduction in the case of such an intervention was as a result of fluoroscopy (heart catheterization lab = HKL) and ultrasound (Tran esophageal Echocardiogram = TEE)

[0012] Despite this auxiliary means, however, it cannot be guaranteed with the conventional solutions that the required lateral accuracy of position, and in particular the angular position of heart valve prostheses, could be accomplished with the anchoring elements appropriately secured on it, where in particular a corresponding angular offset may constitute a threat for the respective patients due to a possible closure of coronary vessels.

[0013] Considerable forces particularly affect an aortic heart valve prosthesis during the filling phase of the cardiac cycle (diastole) so that a secure anchoring is required and a detachment of the heart valve prosthesis and the anchoring elements has to be prevented.

[0014] On this basis it is therefore the task of the invention to find alternatives in order to be able to implant heart valve prostheses with in a minimally invasive manner with increased accuracy of position on a heart chamber of a patient.

[0015] According to the invention this task is solved using a device that exhibits the characteristics of claim 1. Preferred physical embodiments and other studies of the invention can be accomplished with the characteristics indicated in the subordinate claims.

[0016] The device according to the invention

for the implantation and fixing of heart valve prostheses with a heart valve prosthesis fixed to a self-expandable anchoring support is formed in such a way that the anchoring support is accommodated in a folded format, in a cartridge, which can be connected to a catheter. The anchoring support should in the process be composed so that all parts of a certain measurement exhibit extrinsic radial tension, which effectuate the self-expansion following release through a cartridge.

[0017] Anchoring supports with heart valve prostheses may then be implanted together with the cartridge with the assistance of a catheter through a groin artery using conventional methods.

[0018] There are support hoops located on the anchoring supports to be used on the proximal side. These support hoops are then introduced during the actual implantation process into the pockets of heart valves of the respective patient, in the process the pockets of the heart valves of a patient form an abutment so that the proximal insertion movement is counteracted so that the anchoring support can be positioned exactly laterally with the heart valve prosthesis. It is simultaneously ensured that anchoring support and heart valve prosthesis can engage a precise relative position since for this purpose the pockets represent a sort of guide for the supporting hoop during the feeding in.

[0019] The characteristic effects may be accomplished in that exclusively the support hoop of the anchoring support is released as a result of a predetermined first movement of the cartridge and may be directed radially outwards and the other elements of the anchoring supports are kept inside the cartridge still pressed together in the folded form.

[0020] Only after the supporting hoops have been introduced into the pockets of the heart valve of the respective patient and the final position for the implantation has been accomplished are the further elements of the anchoring support released for their full expansion with the heart valve prosthesis, as a result of a second movement of the cartridge and/or of the catheter being used, and anchoring of the anchoring support and a secure fixing of the heart valve prosthesis is accomplished at the most favorable and the best location.

[0021] Abnormal implantations, as were possible with the known solutions, may be ruled out in this way.

[0022] Furthermore, in contrast to the known solutions, there is also the possibility of discontinuing an implantation of a heart valve prostheses destined to be unsuccessful and of removing the device again through withdrawal of the catheter, whereby the support hoop already deployed for this purpose is folded back up again and can be guided back into a cartridge or a part of a cartridge.

[0023] The device according to the invention, however, may also be further composed so that there are additional commissural hoops provided on the anchoring support.

[0024] In the process the commissural hoops count as elements of the anchoring support, which are only released with a second subsequent movement of the cartridge and/or of the catheter for their expansion, if the supporting hoop has been correctly positioned into the pockets of a heart valve.

[0025] During the deployment of the commissural hoop the parts of the old heart valve of the respective patient then reach between each of a support hoop and a commissural hoop so that following successful deployment of the anchoring support, the respective parts of the old heart valve are clamped between both of these hoops, as is similarly the case with a piece of paper between the hoops of a paper clip.

[0026] In particular it is advantageous for the subsequent implementing movements using the cartridge and the catheter and implementing movements, that lead to the sequential release of the individual elements of the anchoring support, to use a cartridge with a plurality of parts, whereby at least two individual parts are able to be moved relative to one another in each case.

[0027] So, for example, the movements of the cartridge or the individual parts of a cartridge to be implemented for the self-expansion may be a proximal and/or distal push, which may occur in several steps to be implemented one after the other, whereby in each case different paths are reserved to release the appropriate parts one after the other at the respective time of an implantation for their expansion.

[0028] So, for example, the first movement may be a distal retraction of the cartridge or a part of a cartridge.

[0029] In this situation then, if this should be required in order to avoid an abnormal implantation, a proximal movement of the cartridge or a part of a cartridge may also be used to fold the support hoop already deployed radially outwards back together again using a pre-stressed force and to accommodate it inside of the cartridge so that a removal of the device from the patient is possible.

[0030] Bowden pull wire or flexible pusher tube, which are guided through the inside of the catheter to the cartridge or a part of the cartridge, may be used as the actuating element for a manipulation and correspondingly a pushing movement of the cartridge or of the individual parts of the cartridge.

[0031] Such actuating elements, however, may also affect the fixing elements, eyelets for example, that are present on the anchoring supports.

[0032] Such fixing elements may also be used alone or in addition for fixing of anchoring supports

on the respective blood vessel.

[0033] In order to facilitate the delayed deployment of the support hoops there may be slits designed on the cartridge, through which a deployment of the support hoop is possible after initialization of the first movement of the cartridge.

[0034] Slits of this type may be configured in the most diverse design, starting from a back side on the cartridge in a straight shape, at obliquely inclined angles or in a curve shape (wave shape).

[0035] The release of the support hoop for its deployment may occur through open slits of a cartridge or a part of a cartridge in the proximal direction if the cartridge or a corresponding part of a cartridge moving in the distal direction, being retracted or, for example, a rotational movement may also be performed about the longitudinal axis of the cartridge so the respective slits are configured in such a way in relationship to the support hoops so that the support hoop can be deployed through the open slits.

[0036] Slits of this type may, however, also be kept covered temporarily through another part of a cartridge, until the slits are released through a corresponding relative movement of the individual parts of the cartridge in the proximal or distal direction respectively, or a rotation about the longitudinal axis, and the support hoops are able to be deployed.

[0037] At this juncture covering web may be configured on the part of a cartridge on which there are no slits configured, which prevents a release of the support hoop until insertion into the pockets in the heart valve of a patient and the release of the support hoop for its deployment can only occur after the corresponding relative movement of the respective parts of a cartridge.

[0038] The support hoops provided on an anchoring support and the commissural hoops as well should be bent in a convex arc in the proximal direction and trauma to the blood vessel on the heart should be avoided as a result of such a rounded shape and the deployment during self-expansion made easier. Likewise, the support hoops may be introduced into the pockets of the old heart valve easier using such a configuration without cataloging corresponding injuries to the tissue or the blood vessels there.

[0039] There may also be additional stabilizing hoops provided on the anchoring supports, with which it is possible to achieve an increase in strength following the self-expansion of the anchored anchoring supports.

[0040] Such stabilizing hoops may be advantageous since small cross-sections for the respective hoop have to be adhered to under consideration of the fact that the smallest volume possible has to be accomplished during the introductory phase of a folded anchoring support inside of a cartridge, for the utilization of the necessary self-expansion effect on an anchoring support for a secure fixing of the anchoring supports with the heart valve prosthesis.

[0041] All of the hoops of an anchoring support should nevertheless be so arranged, configured and dimensioned so that the staged release of the support hoops and the other hoops, if necessary with other elements present on an anchoring support and the heart valve prosthesis can be accomplished through the appropriate manipulation of the cartridge and/or catheter. In the process, of course, the configuration of the cartridge or at least a part of a cartridge should be taken into consideration, which as an example, may apply to the already addressed slits and the web covering these slits.

[0042] Commensurate with the anatomy there should be three support hoops each spaced in the same angular distances to one another on the anchoring supports.

[0043] To that effect there may also be three commissural hoops provided, whereby the minimum number of commissural hoops on an anchoring support has to add up to two.

[0044] The supporting and the commissural hoops may be angularly arranged on an anchoring support in each case in the same relative position so that in each case a support hoop is guided into a pocket of the old heart valve and the part of the heart valve is held by the corresponding commissural hoop in conjunction with the support hoop.

[0045] There is also the possibility, however, that the support and the commissural hoops provided on an anchoring support in each case are offset at an angle to each other.

[0046] In this situation the support hoops in the implanted state are guided into the pockets of an old heart valve with their proximal parts and the old heart valve may then be held clamped in this way using support hoops, so that a commissural hoop with two neighboring support hoops keeps two parts of the old heart valve clamped.

[0047] The stability of an implanted and fixed anchoring support may be increased with the use of at least one annular carrier, which may be an element of an anchoring support.

[0048] So there exists the possibility of connecting a different hoops provided on an anchoring support, preferably at their low ends, with such an annular carrier. In the process it is not imperative to provide a connection between the annular carrier and all of the hoops of an anchoring support.

[0049] An anchoring support with an additional annular carrier may, however, also be designed so that an annular carrier is arranged at intervals to the plane in which the heart valve

prosthesis is fixed to the anchoring support, arranged, for example, with the lengthwise webs. An annular carrier of this type should then exhibit a supporting structure that is z-shaped, undulating or meandering.

[0050] The device in compliance with the invention may also be used in conjunction with a balloon catheter. The old heart valve can be pushed out of the way using the balloon catheter before the self-expansion of the anchoring supports.

[0051] The invention shall subsequently be explained in more detail.

[0052] In the process:

Figure 1 In schematic format shows an example of an implanted anchoring support; a composition of the stent as the anchoring hoop/hook for mechanical stabilization and for exact positioning of the supporting stent of the heart valve is shown.

Figure 2 in schematic format shows an implantation of an anchoring support with heart valve prosthesis;

Figures 3a to 3d four chronological phases in succession during an implantation of a heart valve prosthesis;

Figure 4 an example for an anchoring support in a perspective view

Figure 5 a further example for an anchoring support;

Figure 6 a further example for an anchoring support;

Figure 7 a further example for an anchoring support;

Figure 8 a further example for an anchoring support;

Figure 9 a further example for an anchoring support;

Figure 10 a view of a partially deployed anchoring support inside of a cartridge;

Figure 11 another partially deployed anchoring support inside of a cartridge after figure 10;

Figure 12 A fully self-expanded deployed anchoring support outside of a cartridge after figures 10 and 11;

Figure 13 example of a multi-part cartridge;

Figure 14 a partially deployed, anchoring support in a cartridge after figure 13;

Figure 15 a fully deployed anchoring support outside of a cartridge after figures 13 and 14;

Figure 16 another example of a cartridge;

Figure 17 a cartridge after figure 16 with a partially deployed anchoring support;

Figure 18 a cartridge after figures 16 and 17 with a further deployed anchoring support;

Figure 19 a fully deployed anchoring support outside of a cartridge after the examples in compliance with figures 16 through 18 and

Figure 20 a further example of a multi-part cartridge.

[0053] In a schematic diagram figure 1 shows an example of an implanted anchoring support 1 with a heart valve prosthesis 4 mounted over it.

[0054] Thereby there are supporting hoops 2 provided on the anchoring support 1 shown here, which engage after introduction into the pockets of the old heart valve of the respective patient.

[0055] In addition, there are three commissural hoops 3 provided on the anchoring support 1 here, which also transmit radial forces outwards following the expansion and in the process simultaneously in addition to a certain anchoring effect for the anchoring support 1 clamp the parts of the old heart valve of the patient, that are arranged between the commissural hoops 3 and the supporting hoops 2.

[0056] In the case of the example shown here of an anchoring support 1 this support exhibits on an annular carrier 5 on the distal side, which is designed as a z-shaped supporting structure. This supporting structure also exhibits self-expanding characteristics.

[0057] In schematic format it shall be clarified using figure 2 how an anchoring support 1 may be implanted using heart valve prosthesis 4 transvascularly through the groin artery.

[0058] Using both of the additional sections, as they are shown in figure 2, it should be clarified again, how support hoop 2 of an anchoring support 1, can be introduced into the pockets of an old heart valve of a patient and subsequently following complete expansion/deployment of the anchoring support 1, a stretching of the heart valve prosthesis 4 can be accomplished. It is furthermore shown how the hoops of the stent serve the anchoring and secure placement of the valve-stent-prosthesis in the pockets of the old heart valve to be replaced.

[0059] Several chronological phases in succession during the trans-vascular implantation of a heart valve prosthesis are shown in figures 3 a through 3d.

[0060] Figure 3a shows the trans-vascular introduction of an anchoring support 1 along a guide wire 15, which is folded together in a cartridge 6 in a relatively small volume, whereby the cartridge 6 and a catheter not shown explicitly here, exhibit external dimensions, which are smaller than the inside diameter of the blood vessel used for the trans-vascular implantation.

[0061] The introduction of the cartridge 6 with the anchoring support 1 may be monitored in the process in the conventional format using roentgen radiation and ultrasound technology.

[0062] If in the process the cartridge 6 arrives approximately in the position for the actual implantation a defined predetermined movement is executed on the cartridge 6 or using a catheter, which, as this is explained in figure 3b, leads to the release and deployment of the supporting hoop 2 and in the process this deploys radially outwards. After that the entire device is pushed through the respective blood vessel, traditionally the groin artery or the arteria pulmonalis in the proximal direction so that the support hoop 2 catches hold of the old heart valve of the respective patient and is introduced into the pockets of this heart valve. Upon contact of the proximal end of the hoops 2 with the low points of the old heart valve, a tangible resistance can be felt.

[0063] At least one other movement can then be performed with the cartridge 6 or a catheter, which releases the other elements of the anchoring support 1 and leads to their deployment radially outwards.

[0064] So, as this is explained using figure 3c, through corresponding relative movement of cartridge 6 and anchoring support 1 the commissural hoops 3 are only then delay released for the deployment from the cartridge 6 radially outwards if the support hoop 2 has been introduced into the pockets of the old heart valve of the respective patient. As a result the entire anchoring support 1 with all of its elements is precisely positioned both in the lateral direction as well as in its relative position and a secure fixing of the anchoring support 1 can be accomplished with the heart valve prosthesis 4 as this is shown in figure 3d following its complete deployment and the catheter with the cartridge 6 can subsequently be removed again through withdrawal.

[0065] A few modified examples of anchoring supports 1, which may be used in the invention, should be further explained with figures 4 through 9. In the process similar elements in each case with the same standard references were provided.

[0066] The anchoring support 1, as it is shown in figure 4, aside from the three support hoops 2 essential to the invention, exhibits in the proximal direction extended commissural hoops 3 as well as corresponding stabilization hoops 7, which are all designed in the proximal direction convexly. In this example and in the examples subsequently still to be explained, the low

points of the supporting, commissural and stabilizing hoops 2, 3 and 7 are essentially arranged in the plane, in which the heart valve prosthesis 4 is arranged also.

[0067] In contrast to the example according to figure 4, in which the stabilizing hoop 7 is designed longer in the proximal direction than the commissural hoop 2 and which in turn is designed somewhat longer than the supporting hoop 2, in the case of the example according to figure 5, an extended development of support hoops 2 compared with the length of stabilizing hoops 7 and commissural hoops 3, whose lengths only differ from one another minimally, has been selected.

[0068] The example shown in figure 6 is essentially commensurate with the example according to figure 5. However, the stabilization hoop 7 was dispensed with.

[0069] In the case of the example according to figure 7 extended commissural hoops 3 extended in the proximal direction compared with the supporting hoops 2 were used again.

[0070] In the case of the examples shown in figures 4 through 7 for anchoring supports 1 additional elements, in each case the same, have been used on an anchoring support 1.

[0071] So in each case annular carriers 5 are connected through webs 8 in the lengthwise direction of the anchoring support 1, in each case with the low points of the respective hoops 2, 3 or 7 as the case may be.

[0072] An annular ring of this type is advantageous in the form of a self-expandable support structure, in the case of the example shown designed here as a z-shaped supporting structure, which advantageously causes an even more improved fixing of the anchoring support 1 at the implantation location through application forces effective radially outwards and their design, so that a dislocation or a distortion of the anchoring support 1 with the heart valve prosthesis 4 may be additionally prevented.

[0073] Furthermore, there are fixing elements 9 designed on the anchoring supports 1 on the distal side, here in the form of eyelets. Manipulation elements are able to grab onto these fixing elements 9 so that a dislocation or even a distortion of the anchoring support 1 can be eased as a result.

[0074] In the case of the example according to figure 8 the support hoop 2 and commissural hoop 3 in each case have been used in the same length in the proximal direction. The supporting hoops 2, however, are arranged in an offset angle to the commissural hoops 3.

[0075] The offset angle and the design with dimensioning of the commissural hoop 3 should, however, be selected so that the parts of the old heart valve of a patient are able to be held clamped together with the supporting hoops 2 inserted into the pockets of the old heart valve. So, for example, it may arise that a commissural hoop 3 clamps the parts of two old

heart valve parts of a patient in each case with supporting hoops 2 parts arranged adjacent to this commissural hoop 3.

[0076] In the case of the example shown in figure 9 an arrangement of supporting hoops and commissural hoops 3 selected again with a certain predetermined offset angle was chosen. In the process, however, the supporting hoop 2 is clearly shorter in the proximal direction than the commissural hoop 3 and additional stabilization hoops 7 were provided, which are arranged in the same relative position with the commissural hoops 3. In the process the commissural hoops 3 and the stabilizing hoops 2 differ in their lengths in the proximal direction only slightly.

[0077] There are additional annular carriers 5 available in the examples shown in figures 8 and 9, on which the low points of all of the hoops 2, 3 and 7 are arranged and are able to be engaged. The heart valve prosthesis 4 may then be arranged in a plane in the area of the annular carrier 5.

[0078] In the case of the examples shown in figures 8 and 9 also a further annular carrier 5 is connected through webs 8 with the anchoring support 1.

[0079] Possible embodiments and functions of cartridges 6, which are able to used in devices in compliance with the invention shall be subsequently described as examples with the use of figures 10 through 20.

[0080] Generally, multi-part cartridges 6 are involved in the process. The individual parts of the cartridges may then be moved relative to one another in order to facilitate a sequential release and deployment of the elements of the anchoring supports 1.

[0081] A cartridge 6 is shown in figure 10, on which a proximal end part 6.2 can receive at a minimum the largest parts of hoops 2, 3 and 7 during the insertion process of the anchoring support 1 and other elements of the anchoring support 1 are received in the folded form in a central part 6.1 of the cartridge 6.

[0082] A phase of an implantation of an anchoring support 1 is shown already in figure 10, in which a release of support hoops 2 for their outwards directed radial deployment occurs through a relative movement of parts 6.1 and 6.2, and the supporting hoop 2 has already been introduced into the pockets of an old heart valve. The aortic wall is indicated here schematically.

[0083] The remaining hoops are still inside of the proximal part 6.2 of the cartridge and received in the mid section 6.1 compressed together with their low parts in a folded format.

[0084] The stabilizing hoop 7 and the commissural hoop 3 of an anchoring support 1 were also released in a second movement step, which represents a continuing relative movement between the parts 6.1 and 6.2 of the cartridge 6, and were able to deploy outwards in the radial direction as this implantation

phase stage shall be indicated using figure 11.

[0085] In the process there are parts of the old heart valve of the patient at a minimum between support hoops 2 and commissural hoops 3 and as a result of the forces affected outwards radially of the commissural hoop 3 and the supporting effect of the aortic wall the old parts of the heart valve of a patient are clamped in at a minimum between the supporting hoops 2 and the commissural hoops 3. The stabilizing hoops 7 can support this clamping effect if necessary.

[0086] In figure 12 a stage subsequent to figure 11 again during an implantation of a heart valve prosthesis 4 is shown. The entire anchoring support 1 is released through a retraction of the distal arranged parts of the cartridge 6 and here in particular at a minimum the middle part 6.1 and is able to unfold with self-expansion, whereby the respective heart valve prosthesis 4 is simultaneously unfolded independently of whether a plastic or a biological implant is involved.

[0087] All parts of the cartridge may subsequently be removed and the heart valve prosthesis 4 can immediately assume its function.

[0088] A cartridge 6 with several individual parts 6.1 through 6.6, which receives a folded up anchoring support 1, is again shown in figure 13.

[0089] There is also a proximal part 6.2 provided here, which essentially has to accept the forward parts of the supporting hoops 2.

[0090] Activation elements 10 grasp the proximal part 6.2, in this example Bowden pull wires, for its manipulation and for the triggering of the relative movement for the release of hoops.

[0091] The central part 6.1 essentially receives the other elements of an anchoring support 1.

[0092] The part 6.3 grabbing in the distal direction essentially serves as the receiving element for the activation element 10 for the cartridge parts 6.1 and 6.2.

[0093] The parts 6.4, 6.5 and 6.6 again receive the activation elements through their internal, hollow structuring and through their telescopic arrangement and structuring facilitate an exertion of influence on the relative movements required to be implemented in sequence for the implantation of the anchoring support 1 with the heart valve prosthesis 4.

[0094] Figure 14 again shows a subsequent phase during an implantation of a heart valve prosthesis 4 with an anchoring support 1, in the case of which again a sequential release and deployment of the individual supporting hoops, subsequent to the commissural hoop 3 and supporting hoop 7 for the exact positioning with alignment and to the clamping of the parts of an old heart valve of a patient has been realized as a result of the appropriate movement of the individual elements 6.1 to 6.6 here of cartridge 6 with a plurality of parts.

[0095] Figure 15 then again shows a fully deployed anchoring support after the appropriate relative movement of the individual elements 6.1 through 6.6 of the cartridge 6, whereby the proximal part 6.2 has been separated from the remaining parts of the cartridge and has to be removed separately.

[0096] In figure 16 also a cartridge with a plurality of parts is shown. In the process in the example of a cartridge shown here there is overlaying webbing 6 provided on the proximal part 6.2 of the cartridge 6 in the distal direction. The webbing 11 here is so arranged and dimensioned that as a result of an appropriate relative movement the delayed release of support hoops to be performed during an implantation is able to be accomplished at a minimum of the parts 6.1 and 6.2 and at least of commissural hoops 3.

[0097] This may, for example, in a format now shown, be accomplished through a rotation about the longitudinal axis of the cartridge 6 of the proximal part 6.2, so that here also the slits not shown on part 6.1 are released and a deployment of the support hoop 2 is made possible through the released slits. A relative movement of the elements of the cartridge 6 can then subsequently be performed in the lateral direction for further deployment of the commissural hoops 3 and other elements of the anchoring support 1.

[0098] However, in figure 17 it is shown how a movement triggered in the proximal, lateral direction of the proximal part 6.2 facilitates such a sequential deployment.

[0099] In the process there are slits 12 designed on part 6.1 of the cartridge 6 starting from its proximal back side in the distal direction. The slits 12 were covered beforehand with the webbing 11 of the proximal part 6.2, so that the support hoop 2 had also been held within the cartridge 6 in a folded format.

[0100] After a deployment and introduction of the support hoop 2 into the pocket of an old heart valve has occurred, a continuing movement of the cartridge 6 also leads to the release and deployment effective radially outwards of the commissural hoops 3 and support hoops 7. After further appropriate movement of the distal elements of the cartridge 6 all elements of the anchoring supports are released for their self-expanding deployment as it is indicated using figures 18 and 19 in two phases of an implantation for a heart valve prosthesis 4.

[0101] Modeled on the example as is shown in figures 16 through 19, the example shown in figure

20 of a cartridge 6 exhibits webbing 11, again on the proximal part 6.2 and there may be slits 12 provided on part 6.1, whereby there is no mandatory requirement for slits.

[0102] Activating elements 10 are again indicated in the form of Bowden pull wires in this example.

[0103] The part 6.3 of the cartridge 6 essentially receives the annular carrier 4 commensurate with the structure designed and the part 6.4 serves essentially for guiding of part 6.1.

[0104] Parts 6.5 and 6.5 can potentiate as guides and for the control of the other elements of a cartridge 6 that are needed for the respective movements, which are required for the sequential release and deployment of elements of an anchoring support 1.

Claims

1. Device for the trans-vascular implantation and fixing of heart valve prostheses, with a heart valve prosthesis fixed to a self-expandable anchoring support, characterized in that the anchoring support (1) is accommodated, in a folded format, in a cartridge (6) which can be connected to a catheter; support hoops (2) are formed at the proximal end of the anchoring support (1) and can be introduced into pockets of a patient's heart valve; and, commissural hoops (3) are additionally provided on the anchoring support (1) and, after the anchoring support (1) has been deployed, these commissural hoops (3), along with the support hoops (2), securely hold parts of a patient's heart valve which are each arranged between a support hoop and a commissural hoop (2, 3); by means of a predetermined first movement of the cartridge (6), it is possible for just the support hoops (2) of the anchoring support (1) to be released for introduction into pockets of heart valves, and by means of at least a second subsequent movement of the cartridge (6) and/or of the catheter, it is possible for further elements (3, 4, 5, 5', 7, 8, 9) of the anchoring support (1) with heart valve prosthesis (4) to be released in order to permit complete expansion of the latter and anchoring of the anchoring support (1).

2. Device according to Claim 1, characterized in that the cartridge (6) is formed from a plurality of parts (6.1 - 6.6) which are able to move relative to one another.

3. Device according to Claim 1 or 2, characterized in that the cartridge (6) or individual parts of a cartridge (6.1, 6.2) is/are movable in the proximal and/or distal direction.

4. Device according to one of the preceding claims, characterized in that the cartridge (6) or individual parts of cartridges is/are movable in stages.

5. Device according to one of the preceding claims, characterized in that, in order to move the cartridge (6) or individual parts of the cartridge, Bowden wires or flexible pusher tubes (10) are guided through the inside of the catheter to the cartridge (6) or to a part of a cartridge (6).

6. Device according to one of the preceding claims, characterized in that slits (12) permitting deployment of support hoops (2) are formed on the cartridge (6).

7. Device according to Claim 6, characterized in that the slits (12) are configured as straight lines, at obliquely inclined angles or in a curve shape.

8. Device according to one of the preceding claims, characterized in that the cartridge (6) or a part of a cartridge can turn about its longitudinal axis in order to release the support hoops (2).

9. Device according to one of the preceding claims, characterized in that fastening elements (9) are arranged on the anchoring support (1) for the purpose of transmitting rotation forces, pushing forces or tensile forces and/or for fixing the anchoring support (1).

10. Device according to one of the preceding claims, characterized in that the support hoops (2) and the commissural hoops (3) are curved in a convex arc in the proximal direction.

11. Device according to one of the preceding claims, characterized in that additional stabilizing hoops (7) are provided on the anchoring support (1).

12. Device according to one of the preceding claims, characterized in that the support hoops and commissural hoops (2, 3) are arranged offset at an angle to each other on the anchoring support (1).

13. Device according to one of the preceding claims, characterized in that at least one annular carrier (5, 5') is provided on the anchoring support (1).

14. Device according to one of the preceding claims, characterized in that the support hoops (2), the commissural hoops (3) and/or the stabilizing hoops (7) are connected to an annular carrier (5').

15. Device according to one of the preceding claims, characterized in that an annular carrier (5) which has a z-shaped, undulating or meandering support structure and can be connected via lengthwise webs (8) to support hoops (2), commissural hoops (3) and/or stabilizing hoops (7) is provided on the anchoring support (1).

16. Device according to one of the preceding claims, characterized in that a plurality of parts of a cartridge (6.1 - 6.6) are arranged in the form of a telescope.

17. Device according to one of the preceding claims, characterized in that one part of a cartridge (6) is provided with slits (12), and a second part movable relative to the first part of a cartridge (6) is provided with webs (11) which cover the slits (12) and prevent release of the support hoops (2) before introduction into the pockets of a patient's heart valve.

18. Device according to one of the preceding claims, characterized in that webs (11) protruding in the distal direction are formed on a cartridge part (6.2).

Revendications

1. Dispositif pour l'implantation transvasculaire et la fixation des prothèses de valvules cardiaques avec une prothèse de valvule cardiaque fixée sur un support d'ancrage autoexpansible,
caractérisé en ce que le support d'ancrage (1) est réceptionné dans une forme pliée dans une cartouche (6) pouvant être reliée à un cathéter ;
des étriers de support (2), qui peuvent être introduits dans des poches de la valvule cardiaque d'un patient, sont réalisés du côté proximal sur le support d'ancrage (1), et
des étriers à commissures (3) sont présents en supplément sur le support d'ancrage (1), lesquels maintiennent par serrage avec les étriers de support (2) des parties de la valvule cardiaque d'un patient, qui sont disposées respectivement entre un étrier de support et un étrier à commissure (2, 3), après le déploiement du support d'ancrage (1) ;
seuls les étriers de support (2) du support d'ancrage (1) peuvent être libérés par un premier déplacement prédéfinissable de la cartouche (6) pour l'introduction dans des poches de valvules cardiaques et

d'autres éléments (3, 4, 5, 5', 7, 8, 9) du support d'ancrage (1) avec une prothèse de valvule cardiaque (4) peuvent être libérés par au moins un second déplacement consécutif de la cartouche (6) et/ou du cathéter pour leur expansion complète et l'ancrage du support d'ancrage (1).

2. Dispositif selon la revendication 1, **caractérisé en ce que** la cartouche (6) est formée de plusieurs parties (6.1 - 6.6) qui peuvent être déplacées les unes par rapport aux autres.

3. Dispositif selon la revendication 1 ou 2, **caractérisé en ce que** la cartouche (6) ou des parties individuelles d'une cartouche (6.1, 6.2) est/sont mobiles en coulissement dans une direction proximale et/ou une direction distale.

4. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** la cartouche (6) ou des parties individuelles de cartouches est/sont mobiles en coulissement dans des niveaux.

5. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que**, pour le coulissement de la cartouche (6) ou de parties individuelles de la cartouche, des câbles sous gaine ou des tubes de poussée (10) souples sont guidés à travers l'intérieur du cathéter vers la cartouche (6) ou une partie d'une cartouche (6).

6. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** des fentes (12) permettant un déploiement d'étriers de support (2) sont réalisées sur la cartouche (6).

7. Dispositif selon la revendication 6, **caractérisé en ce que** les fentes (12) sont conçues droites, dans des angles inclinés de façon oblique ou en forme de came.

8. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** la cartouche (6) ou une partie d'une cartouche peut tourner autour de son axe longitudinal pour libérer les étriers de support (2).

9. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** sur le support d'ancrage (1) sont disposés des éléments de fixation (9) pour la transmission de forces de rotation, de poussée ou de traction et/ou la fixation du support d'ancrage (1).

10. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les étriers de support (2) et les étriers à commissures (3) sont incurvés de façon convexe en forme d'arc dans le sens proximal.

11. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** des étriers de stabilisation (7) supplémentaires sont présents sur le support d'ancrage (1).

12. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les étriers de support et les étriers à commissures (2, 3) sont disposés avec un déport d'angle les uns par rapport aux autres sur le support d'ancrage (1).

13. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce qu'**au moins un support annulaire (5, 5') est présent sur le support d'ancrage (1).

14. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les étriers de support (2), les étriers à commissures (3) et/ou les étriers de stabilisation (7) sont reliés à un support annulaire (5').

15. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce qu'**un support annulaire (5) relié au moyen de barrettes longitudinales (6) à des étriers de support (2), des étriers à commissures (3) et/ou des étriers de stabilisation (7) avec une structure de soutien en forme de Z, de forme ondulée ou en forme de méandre est présent sur le support d'ancrage (1).

16. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** plusieurs parties d'une cartouche (6.1 - 6.6) sont disposées sous la forme d'un télescope.

17. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** sur une partie d'une cartouche (6) sont conçues des fentes (12) et sur une seconde partie, pouvant être déplacée par rapport à cette partie d'une cartouche (6), sont réalisées des barrettes (11) recouvrant les fentes (12), qui empêchent une libération des étriers de support (2) jusqu'à l'introduction dans des poches d'une valvule cardiaque d'un patient.

18. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** des barrettes (11) saillantes dans le sens distal sont conçues sur une partie d'une cartouche (6.2).

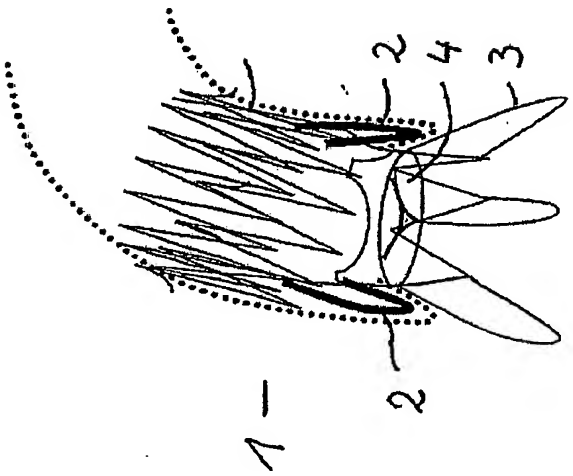


Fig. 1

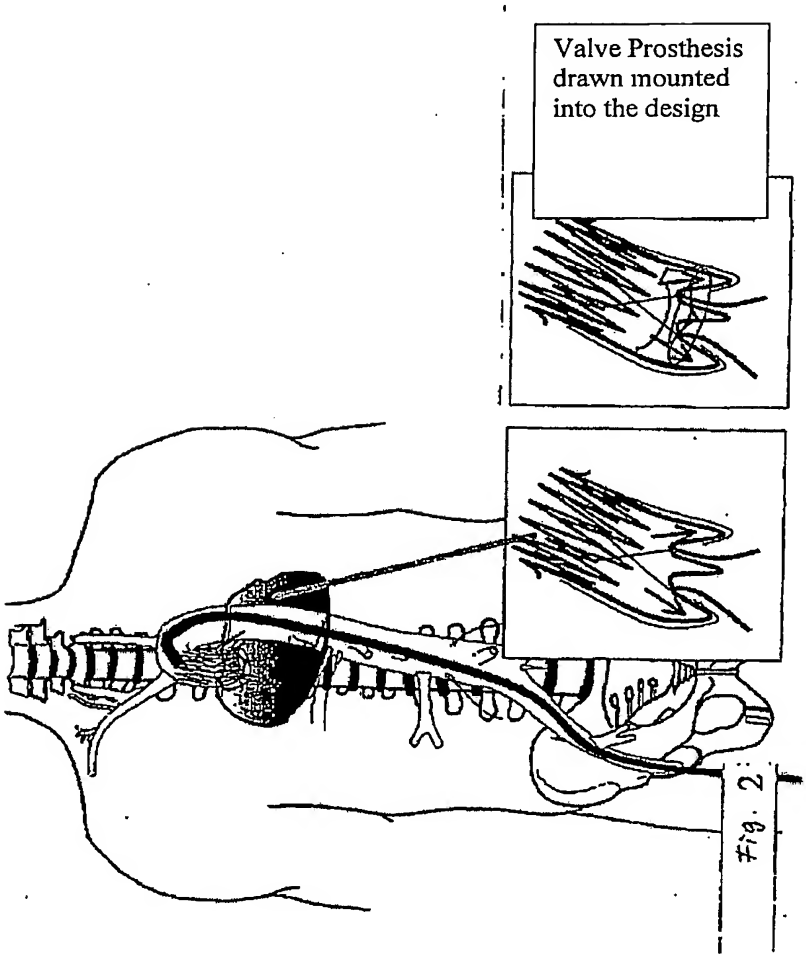


Fig. 2

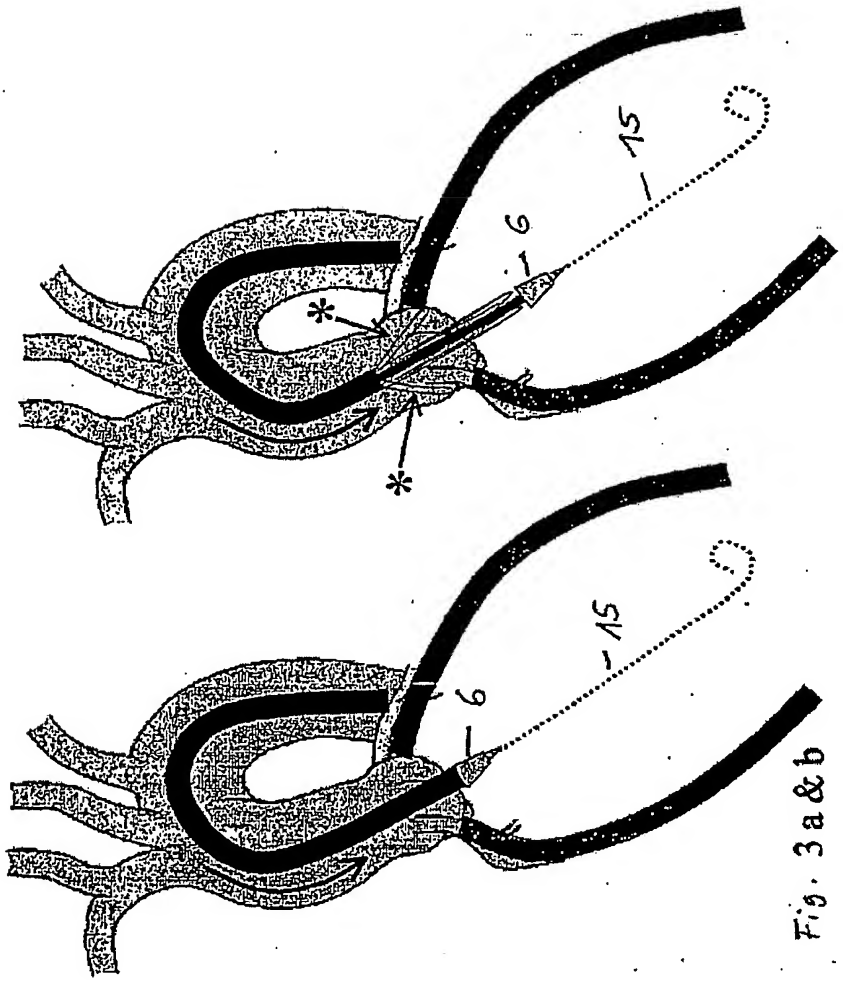


Fig. 3a&b

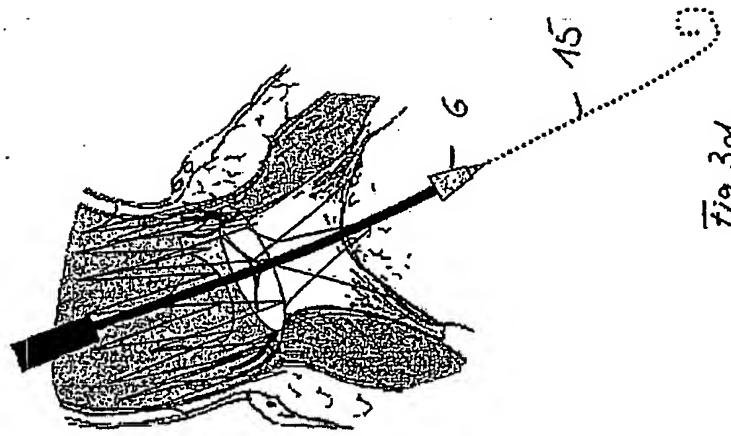


Fig 3d

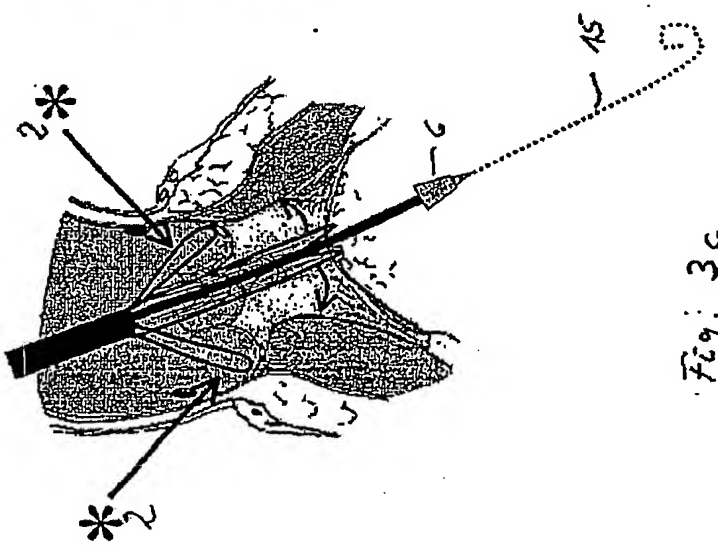


Fig. 3c

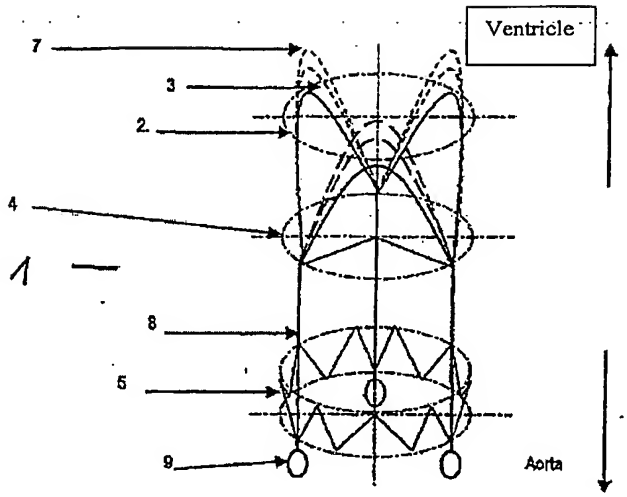


Fig. 4

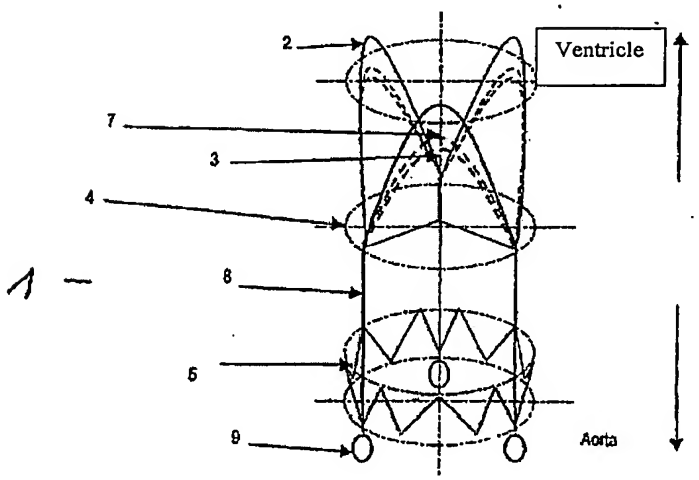


Fig. 5

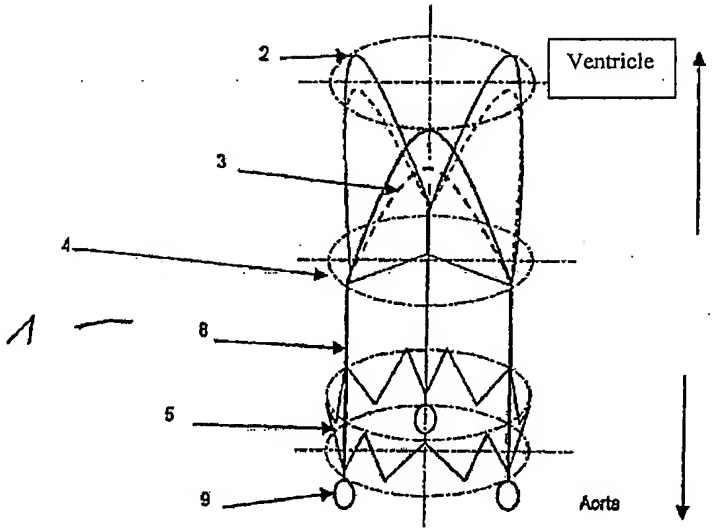


FIG. 6

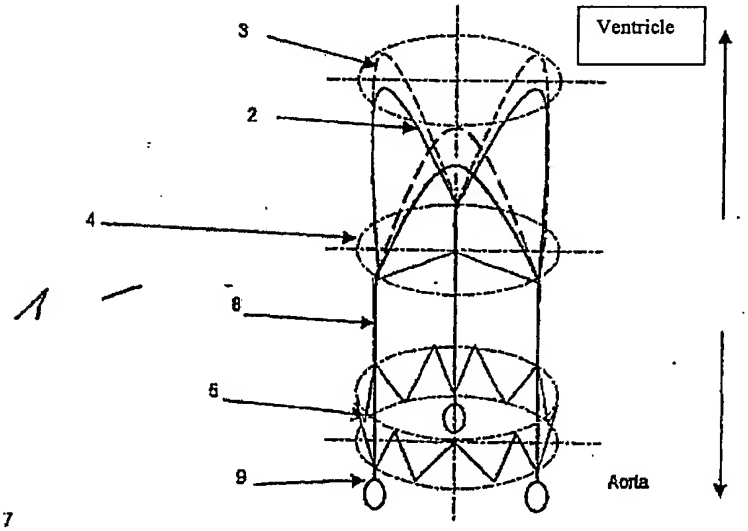


Fig. 7

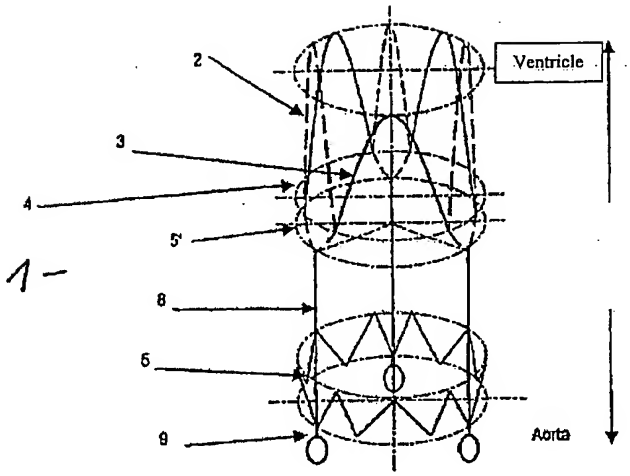


Fig. 8

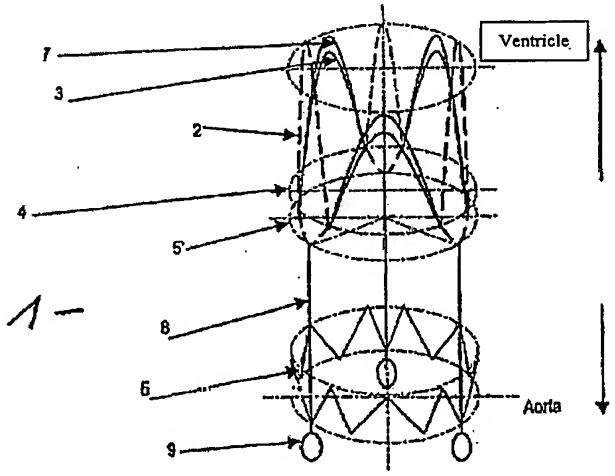


Fig. 9

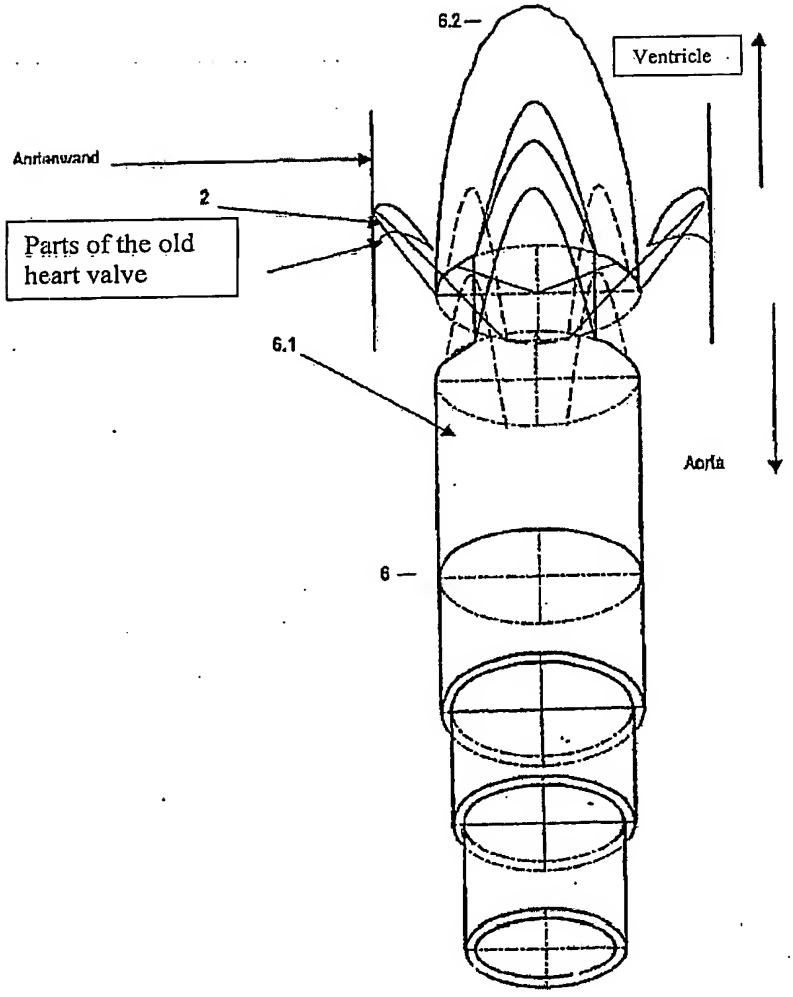


Fig. 10

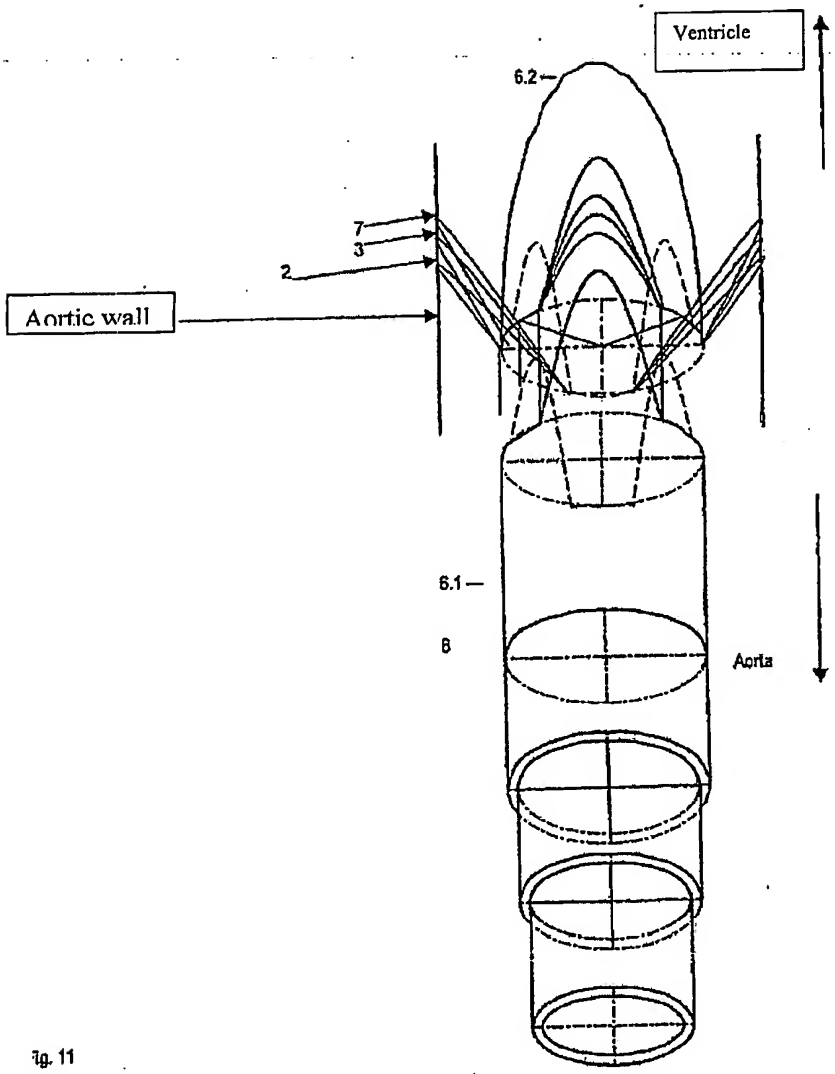
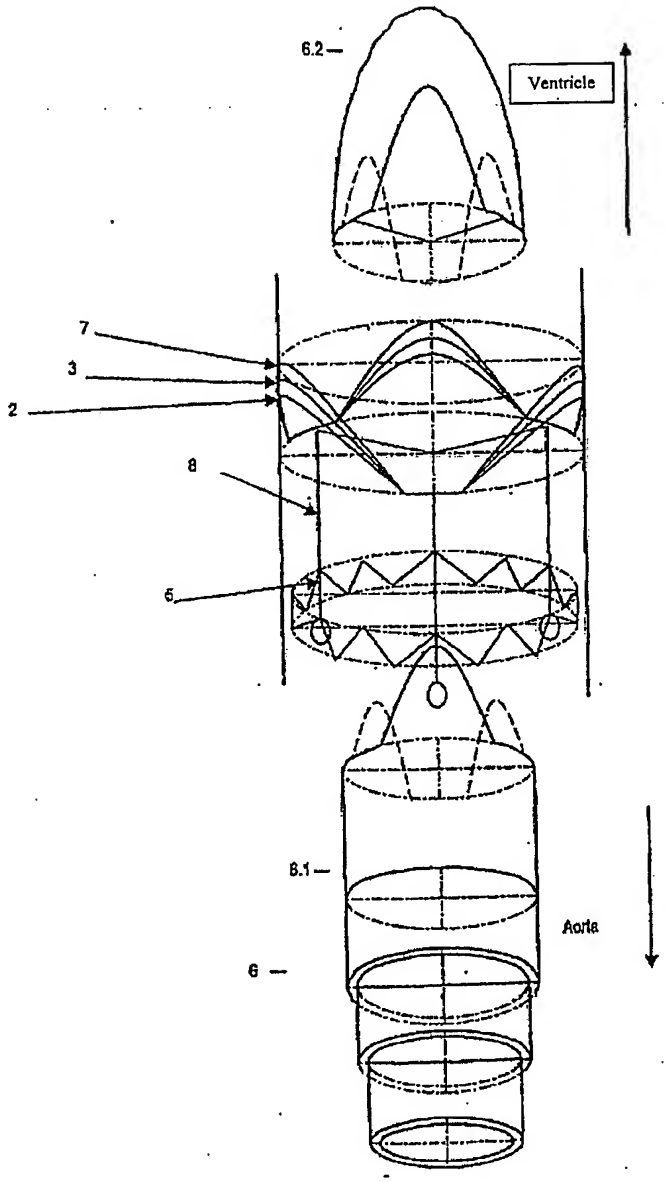


Fig. 11



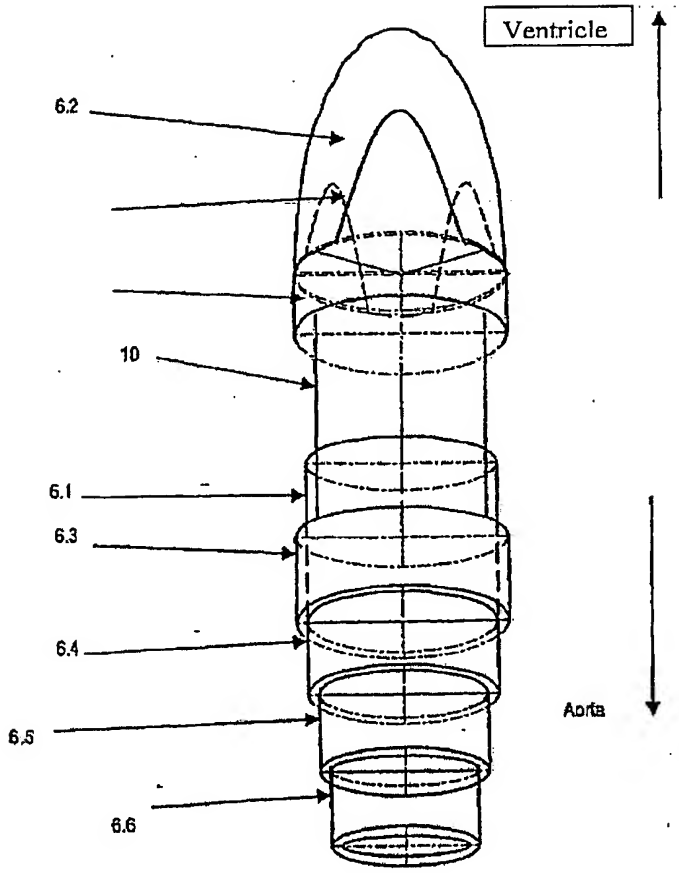


Fig. 13

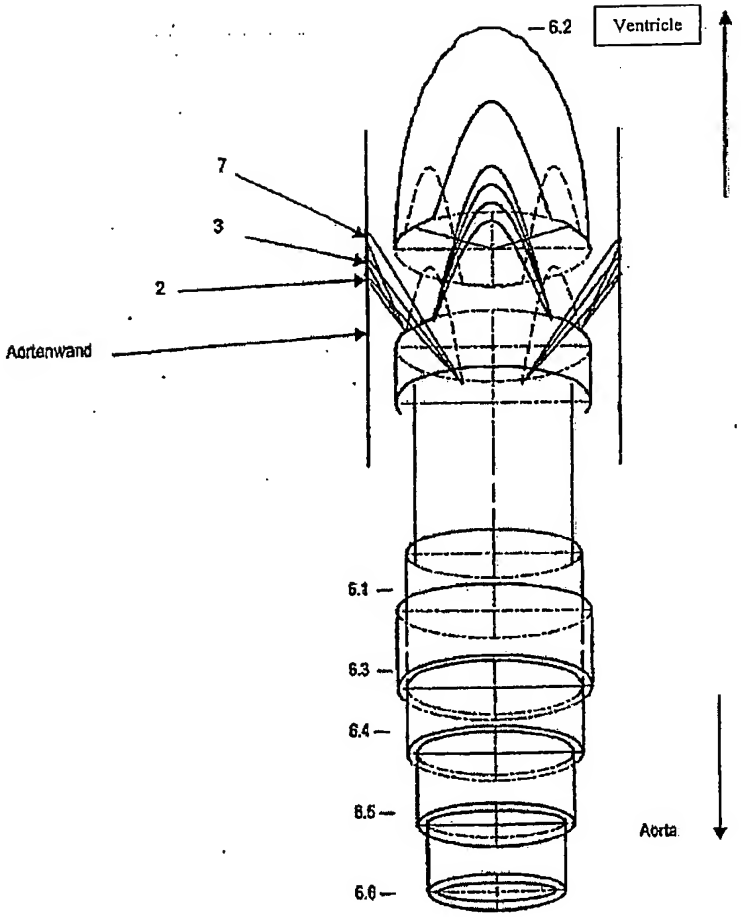


Fig. 14

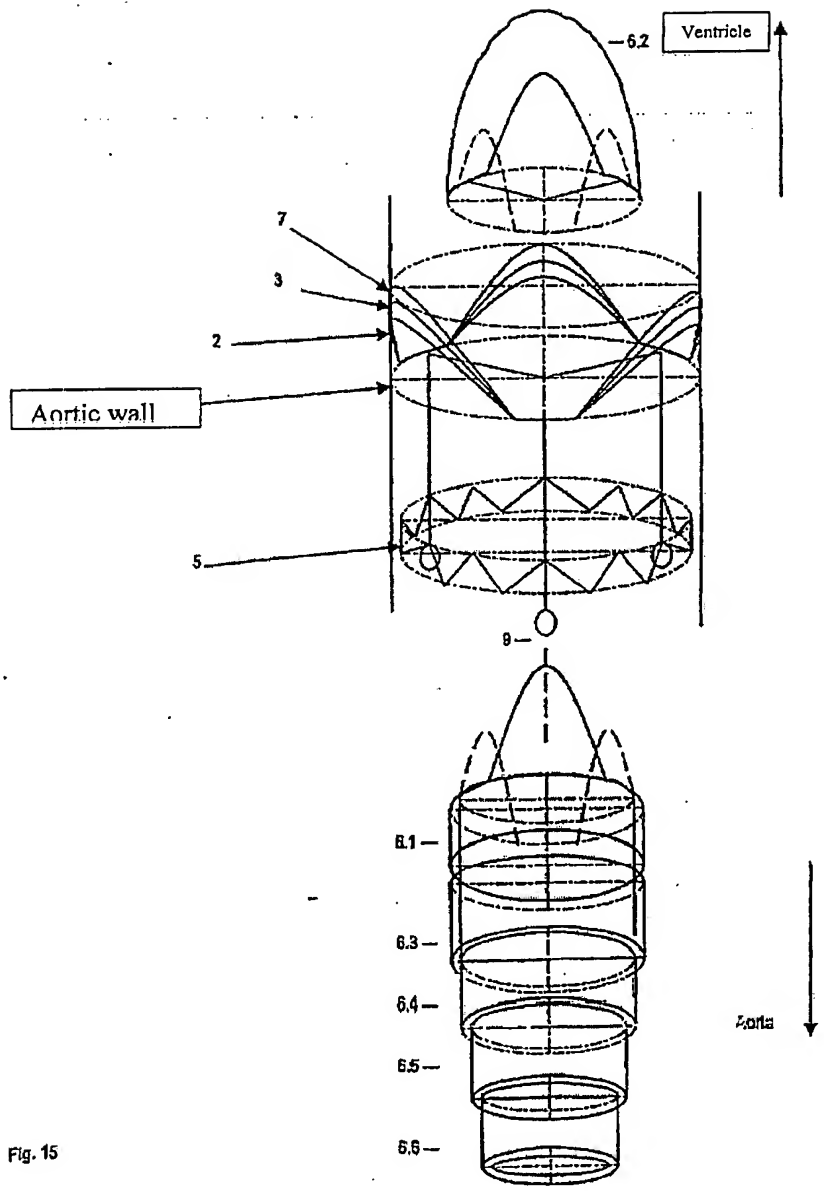


Fig. 15

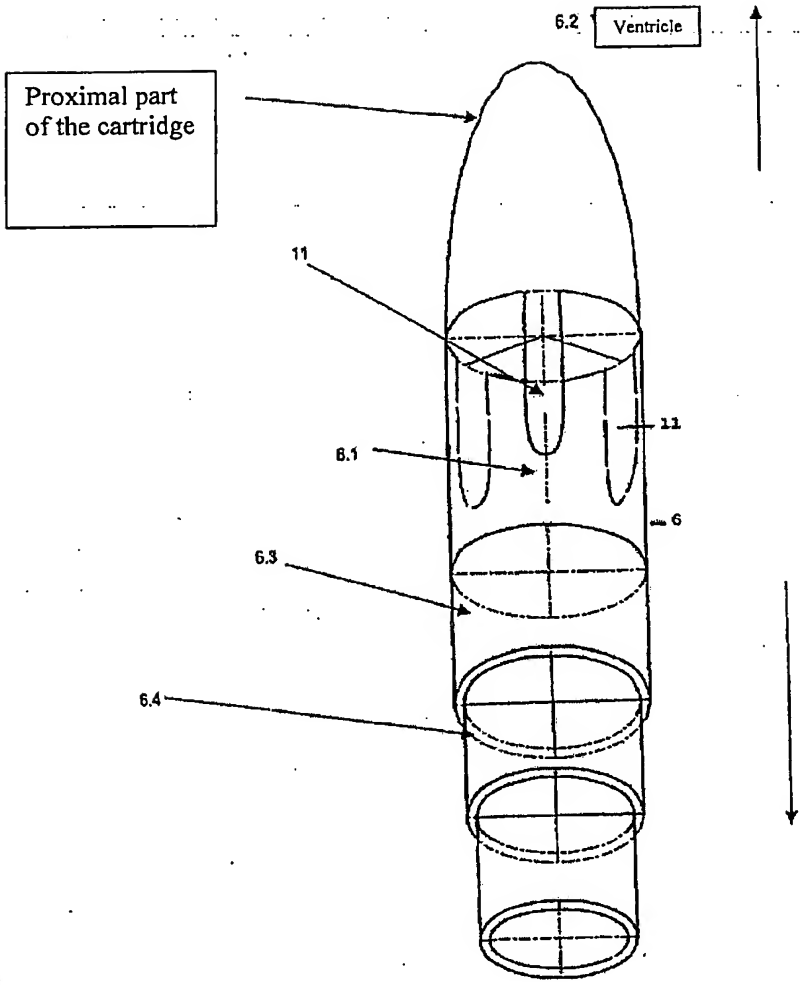


Fig. 16

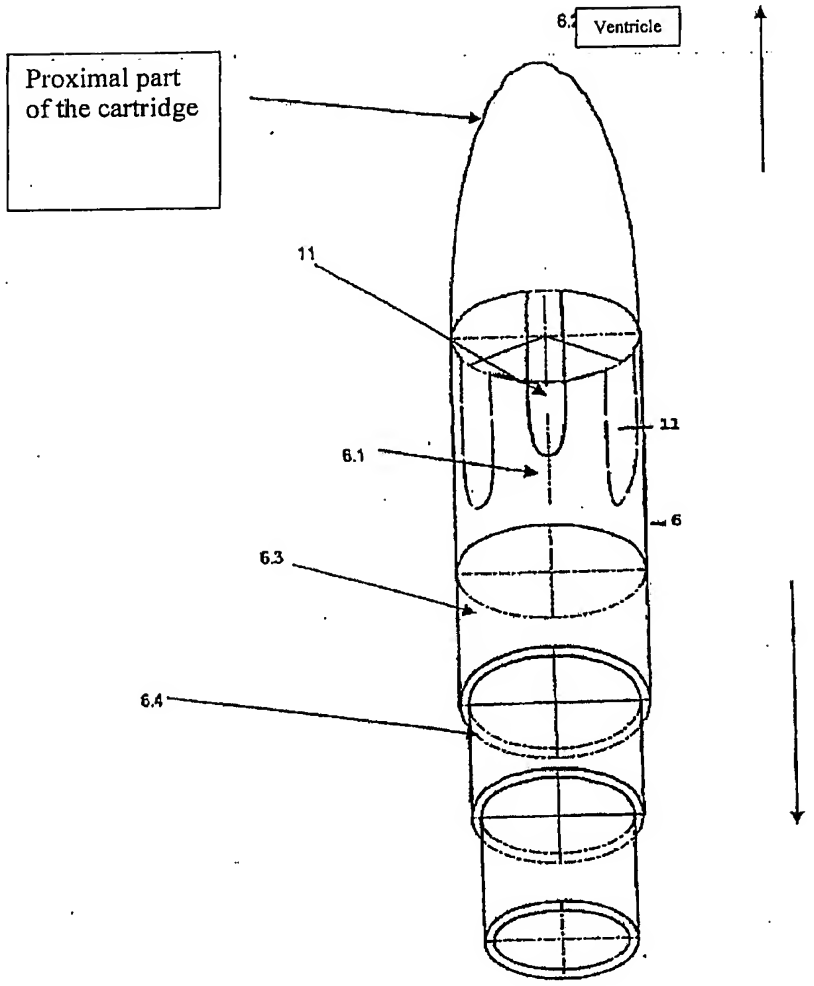


Fig. 16

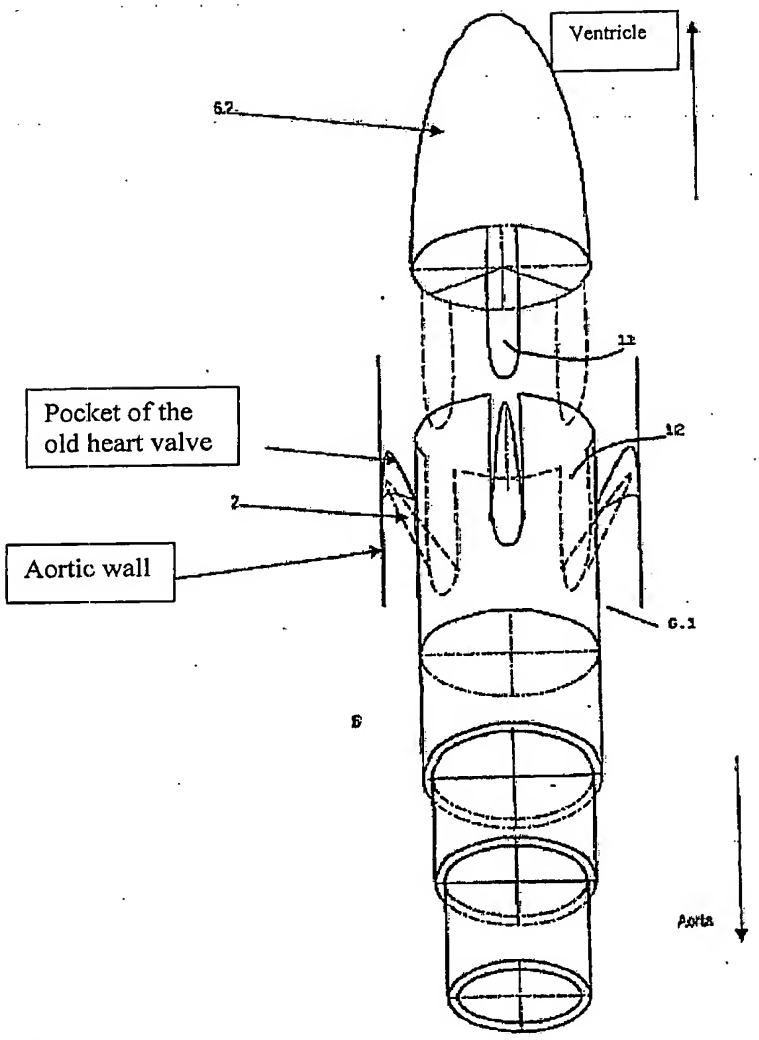

Ventricle
6.2
11
Pocket of the old heart valve
12
2
Aortic wall
6.1
B
Aorta

Fig. 17

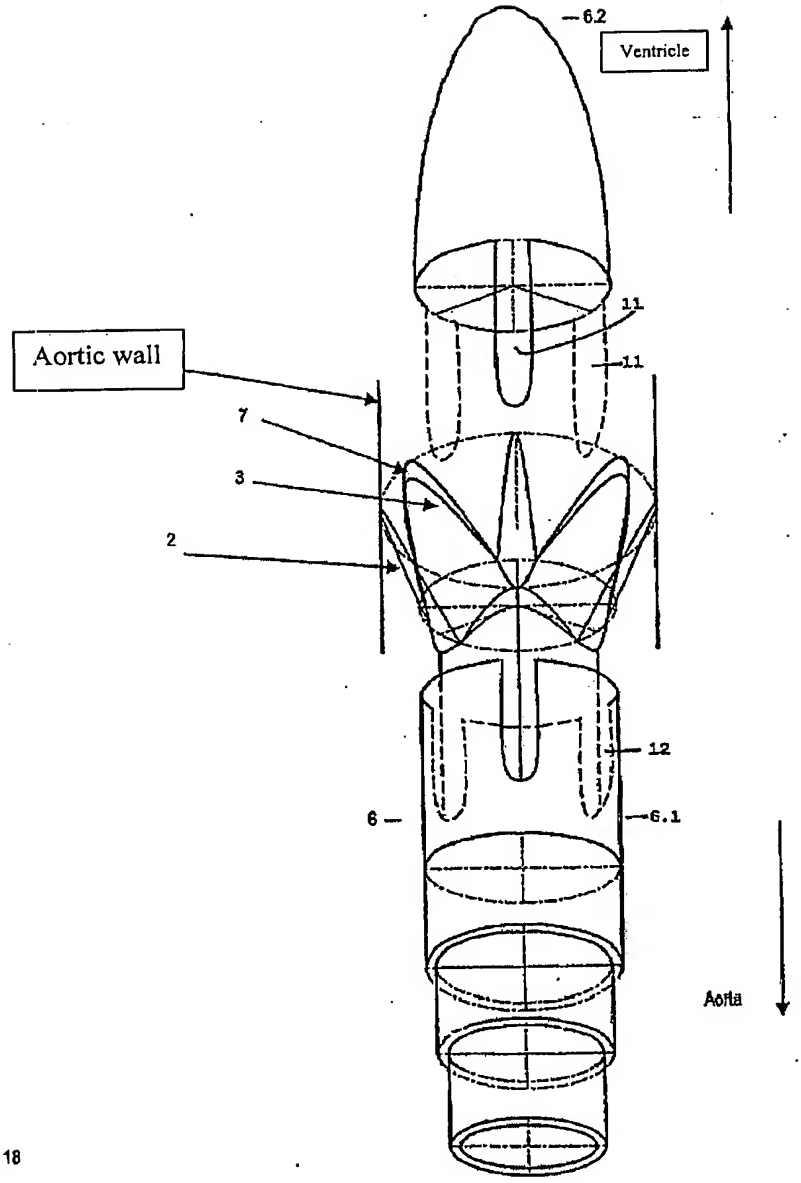


Fig. 18

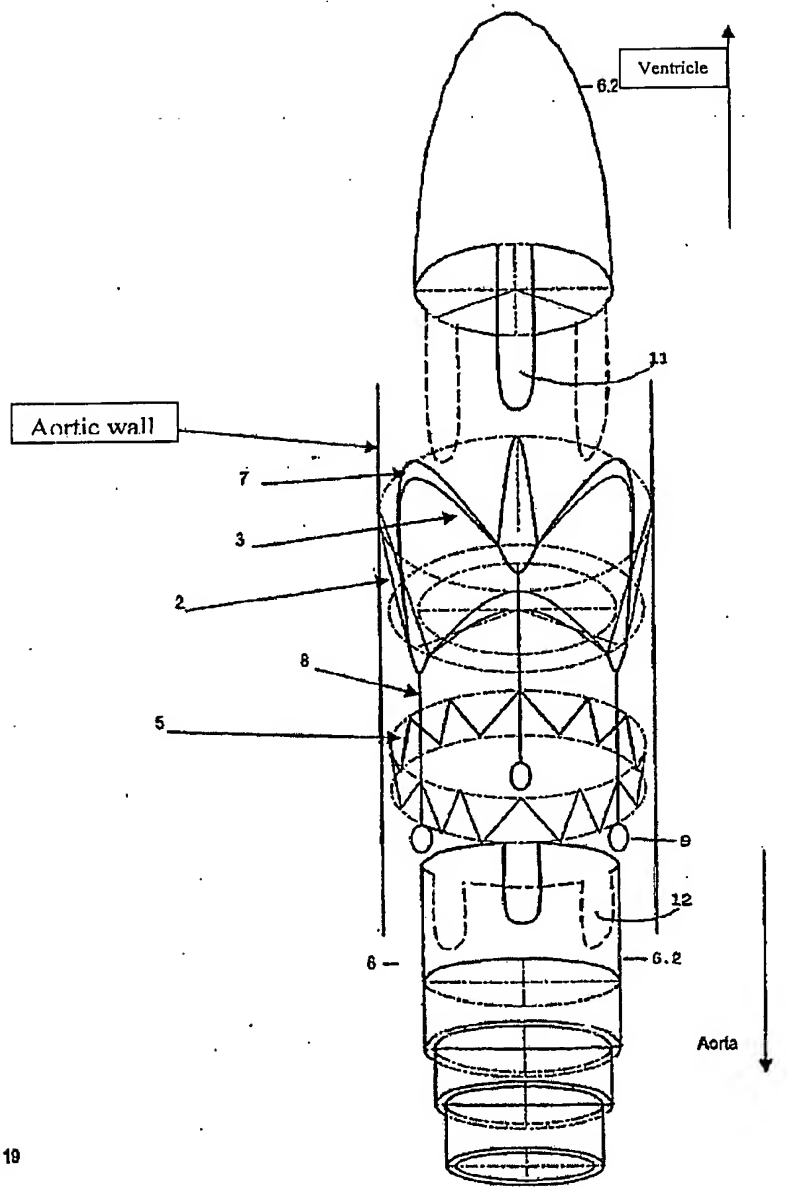


Fig. 19

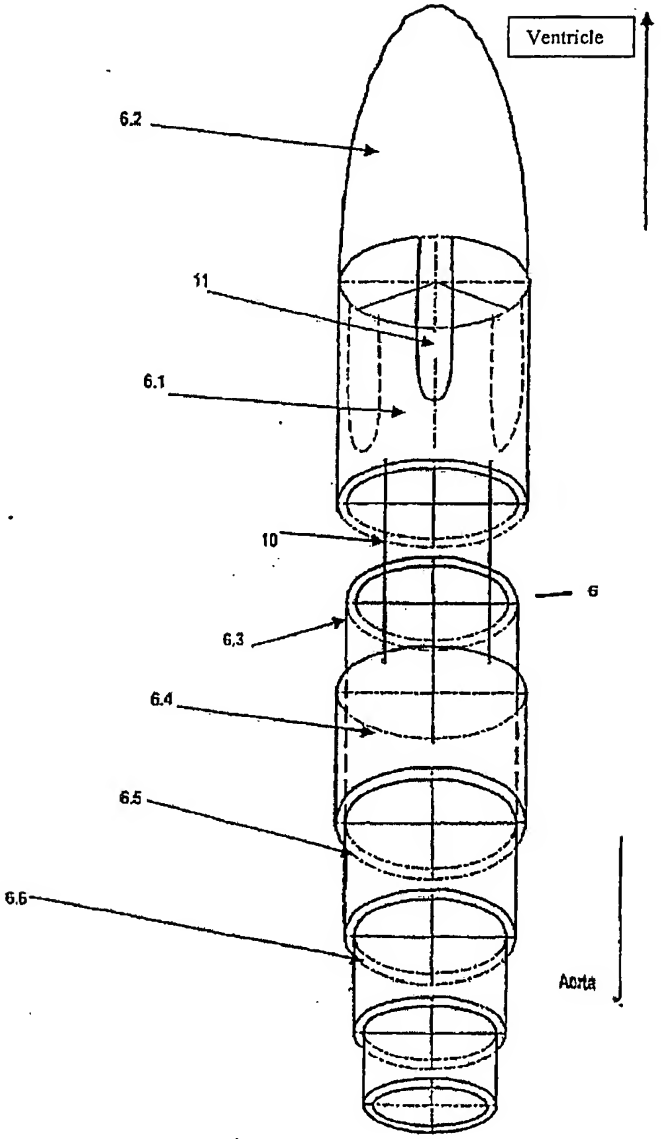


Fig. 20